WHITE PAPER

PPD
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PPD FSP Regulatory Affairs Solutions

Outsourcing Lifecycle Maintenance to a Dedicated FSP Regulatory Affairs Partner

Pharmaceutical and biopharmaceutical developers face many regulatory requirements when bringing a new drug or device to market. However, these requirements extend beyond the approval stage, necessitating ongoing compliance and maintenance throughout the product lifecycle. To ensure adherence to regulations and the continuous supply of drugs to targeted markets, outsourcing regulatory affairs (RA) maintenance activities through a functional service provider (FSP) partnership can prove advantageous.

This white paper outlines:

- Regulatory requirements throughout a product's life, post-approval
- The challenges of lifecycle maintenance
- The benefits of outsourcing lifecycle maintenance activities to an FSP partner

Lifecycle maintenance begins at post-approval

The terms "lifecycle maintenance" and "lifecycle management" are often used interchangeably, though lifecycle management can sometimes refer to the entire development from pre-approval through post-approval. For the sake of clarity, we define lifecycle maintenance as covering all approval and post-approval aspects of a product's lifecycle. This includes critical RA activities such as marketing authorization rollouts and renewals, as well as a wide range of requirements that must be met, from manufacturing or process changes to operational changes, for an approved product.

These lifecycle maintenance activities apply to RA across all types of products or assets (medicinal products, medical devices, drug development, vaccines, etc.) and go well beyond basic regulatory submissions. Lifecycle maintenance is more than just compliance and maintenance for a single market — it is a continuum across all aspects of keeping a product, and product range, in the market for many years and throughout multiple countries.

- Maintaining the continued presence of a product in the market requires compliance with global standards for safety and quality. This involves implementing good manufacturing practice (GMP) to avoid situations where a product may be deemed out of specification, out of trend or prone to safety and quality concerns that could lead to a recall. Additionally, it is important to minimize variations in manufacturing processes to optimize cost-effectiveness. Further, maintaining a strong commitment to brand identity is crucial, as it reflects the product's quality, effectiveness and safety.
- Maintaining the product range encompasses various activities related to product expansion. These include line extension (modifying an approved product in terms of its form or strength), geographical extension (introducing the product into new areas) and customer extension (targeting new patient groups).

Lifecycle maintenance entails constant monitoring to ensure compliance as regulations and other requirements change, and to ensure timely and consistent updates of quality and safety information. To develop a regulatory strategy that is proactive and can effectively enhance value, manage costs and ensure compliance, it is essential to have an RA team that possesses comprehensive knowledge in various aspects of business operations and law, including:

- Contract law
- Patent law
- Trademark, copyright and design law
- Laws relating to restrictive or unfair trade
- International law
- Tax- and revenue-related law

In many ways, lifecycle maintenance can be viewed as "factory work," i.e., routine submissions in support of changes to manufacturing, market expansion, safety and quality reporting of the drug or device. In this sense, lifecycle maintenance produces hundreds of high-quality dossiers in the shortest time possible, all while managing shifts in planning and priorities.

Challenges of effective lifecycle maintenance

For pharma/biopharma manufacturers, lifecycle maintenance is a top priority. While the overall market has seen an increase in new drugs (in the U.S., the FDA approved 55 novel therapeutics in 2023, the second highest count in 30 years), those numbers fluctuate from year to year and are a variable revenue stream when compared to the sale of existing products. Increased competition and ongoing pressure from generics and other innovative presentations is further pushing drug developers to focus on return on investment (ROI), often by increasing efficiency and reducing manufacturing, marketing and distribution costs. Many of these ROI-focused efforts, however, include a significant need for RA maintenance activities.

For all manufacturers, but even more so for those with large portfolios of products in multiple countries or markets, lifecycle maintenance can be burdensome. Among the major challenges is the need for deep knowledge of the product along with long-term focus and commitment to ensure consistency through the years. Although the development phase often takes 8-10 years, this may be a short duration compared to the decades that a product spends on pharmacy shelves.

Drug developers that rely on an internal RA team to handle lifecycle maintenance also face the challenge of staffing an ever-changing workload. Tasks related to lifecycle maintenance inherently ebb and flow, with major peaks during times of change interspersed with intervals of inactivity for a particular product. Consider a relocation of corporate headquarters or a change of manufacturer (a common late lifecycle move). Such situations can induce a cavalcade of updates and revisions across the company's entire product line, in every jurisdiction where those products are marketed.

The regulatory team's workload can be significantly increased by any type of change, regardless of its size. This could overwhelm an in-house RA group if not managed properly. It is crucial to plan carefully and accurately forecast the workload to avoid situations where the team is overloaded one week and lacking tasks the next. Additionally, certain tasks may be too challenging for junior staff members while being too mundane for senior staff members.

In-house RA teams may also face challenges from, and contribute to, inconsistencies and delays caused by corporate units or enterprises. In large pharmaceutical or biopharmaceutical companies, different teams may be responsible for managing various products. This can result in crucial information being isolated within one group, potentially located in a different country and in a different language.

These challenges pose a significant risk of noncompliance for the drug manufacturer, potentially leading to the removal of a product from the market(s). Even a temporary removal can have serious consequences, impacting the company's relationship with health authorities, revenue and overall brand reputation.

FSP outsourcing of lifecycle maintenance offers significant benefits

Using a trusted FSP partner to handle RA across lifecycle maintenance is a proven, cost-effective approach to overcoming the above challenges and minimizing product disruptions in the marketplace. By outsourcing the RA burden, pharma/biopharma companies can focus on discovering and designing new medicines while delegating routine yet critical maintenance to a dedicated partner with extensive regulatory expertise. Typically, one FSP RA team will provide oversight across the client's many products and across all relevant markets. This approach is key to breaking down information silos and can improve accuracy and efficiency during even the most complex undertakings.

By making RA a key component of its partnership capabilities, the FSP partner also takes over the burden of acquiring and maintaining a highly skilled workforce with experience across global markets. An outsourced RA team should be flexible and ready to work however the customer requires, and seamlessly blend with the full range of internal teams to eliminate barriers and ensure timely execution of all tasks.

Today's leading FSP partnerships are also global in nature, meaning they can employ a follow-the-sun model that ensures projects proceed around the clock and experts can be contacted at any time, no matter the company's home country or time zone. This model ensures timelines are met and improves ROI by using global resources across cost-efficient locations, whether or not the client is in the same region.

Working with an experienced FSP partner also enables the drug developer to take advantage of specialized technologies and systems that may be difficult to create in-house. For example, our PPD FSP Regulatory Affairs solutions provide a proprietary intelligence platform, PPD RegView, that facilitates use and sharing of clear, comprehensive regulatory information across more than 100 countries. The RegView platform includes intelligence across various stages of development, clinical requirements and post-marketing lifecycle data in many countries. This enables our PPD FSP Regulatory Affairs solutions teams to capture a wide range of country-specific regulations and procedurals guidance quickly and efficiently, including:

- Legislation/regulations, processes and timelines
- Industry practices
- National/regional differences
- Regulatory analysis
- Regulatory precedence
- Guidelines/directives
- Opinions/advice
- Contemporary experience

In an ideal scenario, the drug developer views its regulatory FSP as a valuable strategic partner. This is only possible when the FSP partner possesses a wealth of experience and offers insightful guidance. It is crucial that the pharma/biopharma company trusts its FSP partner, as the FSP partner is responsible for ensuring that products remain accessible and able to generate consistent and dependable revenue. By leveraging the expertise and experience of an FSP partner, the drug developer gains an advantage across many aspects of its business, including planning and strategy development.

The FSP model ensures uninterrupted product lifecycles

Lifecycle maintenance is critical to ensuring a therapeutic product's long, uninterrupted life in the market. However, the long span of years over which therapeutic drugs and devices are available creates challenges, increasing the need for RA activities across decades and throughout geographically diverse markets. By engaging with an FSP partner, the pharma/biopharma developer can offload a significant amount of regulatory burden. Rather than struggle to meet lifecycle maintenance needs in-house, developers can take advantage of the FSP partnership model to outsource that regulatory workload to a team of dedicated specialists with the experience and expertise to maintain consistency and compliance in the face of constant change.

An FSP partner ensures steady outcomes even as lifecycle maintenance tasks ebb and flow. By seamlessly blending with the client organization, the FSP partner ensures the client's processes and procedures are not disturbed, while continually keeping personnel aligned with ever-changing needs for knowledge, experience and manpower.

Our Solutions Provide Unparalleled Support to Guide Market Access and Regulatory Approval Success

Our PPD clinical research business supports customers' ability to advance their discovery of new drugs.

We do this in part through our PPD FSP Regulatory Affairs solutions, which provide dedicated RA leads and strategists who often remain in these roles for years. With a core focus on helping our clients navigate regulatory approval and market access for their products, our comprehensive end-to-end regulatory solutions integrate with and become an extension to a company's own regulatory group. Our solutions provide much-needed resource flexibility, reliability, and continuity through a scalable approach that brings the right resources at the right time to create an effective pathway to staffing at optimal levels, even as workloads fluctuate.

Our team's vast experience with health authorities facilitates good relationships and increase the probabilityof success, while our industry-leading knowledge and expertise engenders client trust and the ability to deliver strategic influence. It is this trust that empowers our teams to largely self-manage the lifecycle maintenance needs of some of the largest drug developers in the world.

Our PPD FSP RA solutions have a 30-year record of success in delivering lifecycle maintenance capabilities to many large and small pharma/biopharma partners. Our dedicated RA experts provide regulatory strategy, intelligence, and delivery – across the entire product lifecycle – with the ease and convenience of a single global partner and work seamlessly across all functional areas (CMC, clinical, labelling, safety, etc.). We operate in multiple countries and deliver critical expertise in all aspects of RA necessary to maintain products on the market, including:

- Operational and strategic experience and global reach
- Expertise in planning, forecasting and submitting regulatory submissions, including liaising with competent authorities
- The ability to establish and maintain long-term partnerships and adjust to evolving client needs
- Technical and regulatory proficiency to reduce risk of license non-compliance and loss efficiently and cost-effectively.

In the last five years, we have delivered:

- 5,200 North America lifecycle submissions
- 21,000 rest of world lifecycle submissions
- More than 34,900 lifecycle submissions (more than 63,000 since 2006)
- For one client alone, we have delivered:
  - 54,000 lifecycle maintenance submissions for 54 products in 165 countries
  - Post-approval maintenance of more than 4,000 licenses
  - A 25% cost savings by way of improved efficiencies and low-cost resourcing
  - Up to 60% reduction in time and cost per unit (in just five years of partnership)

Our strategic regulatory services span the full spectrum of activities and technical functions so your project can be supported in regulatory development, licensing and life-cycle management, regulatory strategy input, and full-service regulatory partnerships. Regular deployment of process improvement techniques and use of the latest technology ensures quality of delivery.

[1]Novel Drug Approvals for 2023, U.S. Food and Drug Administration. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023

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